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14. ABSTRACT Prostate cancer (CaP) is the second leading cause of cancer mortality, and both recurrence and mortality rates are significantly higher in African Americans (AA) than Caucasian Americans (CA). Research suggests that CaP may be affected by lifestyle factors (e.g. diet, dietary supplement use and physical activity) after CaP diagnosis and the effects of these changes on CaP prognosis. Interviews and biological samples will be collected over a period of 2 years from 125AA and 125CA diagnosed with CaP. UNC-CH IRB approval was granted in February 2005. All task 1 actions in the statement of Work have been completed, including hiring a project manager and developing a Lifestyle Changes Questionnaire, a Dietary Recall Script and study communications materials. A HIPAA compliant tracking system has been designed and is under construction. Tasks 2-15 in the Statement of Work refer to participant enrollment, data collection and data analysis. The study is awaiting DoD HSRRB approval to begin enrollment and data collection.					
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I. Introduction

Prostate cancer (CaP) is the most common cancer in men and the second leading cause of cancer mortality. African Americans (AA) have the highest CaP incidence and mortality rates among all racial/ethnic groups ^{1,2}, and CaP recurrence rates after definitive treatment are significantly higher in AA than Caucasian Americans (CA) ²⁻⁵. Studies indicate a link between CaP prognosis and lifestyle factors, e.g., diet, physical activity, and dietary supplement use ^{2, 6-8}. However, little is known about lifestyle behavioral patterns among men diagnosed with CaP, and there are no data on racial differences. This project tests the hypothesis that men diagnosed with CaP modify lifestyle factors (dietary intake, physical activity, and dietary supplement use) differently by race, which alters prognosis. Specifically, AA diagnosed with CaP make fewer healthy changes than CA, which might contribute to worse prognosis among African Americans. To test these hypotheses interviews and biological samples will be collected over a period of 2 years from 125 AA and 125 CA age 40-80 years diagnosed with pathologist-confirmed, histologically diagnosed CaP and enrolled in the PCaP Consortium study, a DoD-sponsored multi-center case-only study of CaP patients. The current study will assess whether alterations in diet, dietary supplement use and physical activity upon a diagnosis of CaP are associated with oxidative DNA damage in lymphocytes (an objective marker of the dietary effects) and changes in CaP prognosis, using serum prostate specific antigen (PSA) as a marker of disease progression. Combining careful assessment of diet

and other behavioral CaP risk factors with the collection of biological samples will permit this study to thoroughly examine their effects on CaP prognosis.

II. Body

The original budget for the award was revised in May 2004 to reflect changes in methodology used in the baseline PCaP study that are also being used in the follow-up study. For example, the baseline PCaP study decided not to use a computer-assisted diet history interview tool and instead is using a paper scannable Food Frequency Questionnaire, thus this 250 PCaP Follow-up Study needs to use the same instrument in order to make the comparisons needed to assess dietary change. The revised budget was approved and funds were released from the DoD starting July 1, 2004.

Referring to the Statement of Work, all action items under Task 1 have been completed. A project manager, Sandra Duvall, MA, was hired in January 2005. Ms. Duvall is an experienced study coordinator and is a valuable asset to our team. Additionally, regarding personnel hires, a doctoral student from the Department of Nutrition who is supported by an NIH Nutrition, Energetics and Cancer Training Grant, will be joining our team in August 2005 to assist Ms. Duvall in daily operations of the study. We have not hired a phlebotomist/interviewer yet as we are awaiting HSRRB approval before we can begin collecting data. However, we have been discussing the possibility of hiring a nurse part-time who would also work part-time for the PCaP Consortium. We

believe this would be a very efficient way to fill our position since the protocols for the two studies are so similar (i.e. from our study's perspective there would be less time spent on training since the nurse would already be trained in the interview and biologic sampling methods of the PCaP study). Once we receive HSRRB approval, we will hire a nurse and begin data collection.

One new questionnaire was developed for this follow-up study, a Lifestyle Changes Questionnaire (see Appendix A) to directly assess changes in diet, supplement use and physical activity at the 12-month and 24-month post-diagnosis in-home visits. Additionally, since three 24-hour dietary recalls will be performed between months 6 and 12 post-diagnosis, a Dietary Recall Script (see Appendix B) was needed and developed. Study communication materials, including letters inviting PCaP participants to enroll in the 250 PCaP Follow-up and appointment reminder letters, were developed and submitted to the UNC-CH Institutional Review Board (IRB) and the DoD HSRRB. Local IRB approval for the protocol and all questionnaires was obtained in February 2005. The protocol and questionnaires were submitted to the DoD HSRRB, and the application is pending. Modifications to the protocol, including a telephone consent script for the dietary recalls (see Appendix C), were submitted to the UNC-CH IRB and approved in May 2005. The updated protocol was submitted to the DoD HSRRB in May 2005.

The PI and project manager have met frequently with investigators on the PCaP Consortium study (Joseph Su, Jeannette Bensen, Jane Schroeder, Peter DeSaix and Diane Baker) for assistance in developing IRB materials, a website where

investigators and potential participants can learn more about the study, and the subject and specimen database and tracking system materials. The tracking system for participant recruitment, acquisition of biological samples, and collection of self-reported data was designed in May 2005 and will be developed and implemented in July 2005. The tracking system is designed to be integrated into the PCaP Consortium database, which is constructed on secure servers using best practices to ensure HIPAA compliance. A unique subject identifier (ID) is generated for each subject from this computer-based tracking system.

The central subject and specimen tracking systems are built atop a medium-scale Oracle database served by a pair of redundant, fail-over servers that are maintained 24x7 for optimal availability. Consortium staff access the data in the Oracle tables via ODBC interfaces in applications like Microsoft Access, PHP/web, and SAS. Data streams between client machines and the server are protected from compromise accordingly. Connectivity within the UNC Network utilizes protections built into our enterprise switched network fabric. All access via web browsers is restricted to Secure Sockets Layer (SSL) connections.

The specimen tracking system records the location and processing of all specimens: cradle to grave. Specimens gathered in the field will be immediately linked to subjects via barcode labels. A "check-in" process will introduce a specimen record into the database system. All aliquoting and processing will be recorded, including genealogy and descriptors (volume, concentration, etc.). Users will be able to view specimen records from at least three perspectives: a subject-perspective will provide a view of all specimens associated with a

selected subject; a specimen-perspective will give all details of an individual specimen (subject ID, specimen type, storage location, date collected, volume, etc.); and a box-perspective will give details about a selected storage box (contents, location of box, shipping status, etc.).

All tracking data will be stored as Oracle databases, and the questionnaire data will be converted to SAS datasets. The analytical SAS datasets will be subject to data cleaning, QC reporting, and any other analysis as may be required. The servers hosting the data use RAID technology and are powered by Enterprise level UPSes to protect the integrity of the data. These servers are backed up daily as part of the School's business continuity plan.

Regarding Task 2, as mentioned above, the study has obtained IRB approval from the UNC-CH IRB, and is awaiting HSRRB approval before obtaining names of the eligible participants from the PCaP Consortium and beginning to contact them by mail and telephone to solicit participation. Following participant enrollment, the study will begin conducting three 24-hour dietary recalls by telephone for each participant prior to their 12-month post-diagnosis in-home visit. In-home interviews and data collection are anticipated to begin in September of 2005.

Tasks 3 through 15 in the Statement of Work all refer to data collection and analyses activities which have not begun yet.

III. Key Research Accomplishments

The study is awaiting DoD HSRRB approval before beginning data collection. As such, there are no key research accomplishments to date.

IV. Reportable Outcomes

This study is awaiting DoD HSRRB approval before beginning data collection. As such, there are no reportable outcomes to date.

V. Conclusion

The study-design and set-up, including protocol, questionnaires and tracking system development, are on target. Participant recruitment and data collection are ready to begin upon DoD HSRRB approval. The design of the follow-up study is to interview and collect biologic specimens from PCaP participants beginning between 6 and 12 months following prostate cancer diagnosis through 24 months post-diagnosis. It is anticipated that recruitment and enrollment of subjects will begin in July 2005 and continue through February 2006. Final visits with all 250 participants are expected to be completed by August 2007.

The anticipated timeline is as follows:

Date	Activity
December 2004	IRB submission to local UNC-CH IRB
February 2005	Revisions and approval from UNC-CH IRB
March 2005	Submission of HSRRB application
July 2005	Final IRB approval from HSRRB
July 2005 – February 2006	Recruitment and enrollment of all 250 subjects, mail and telephone contact
July 2005 – July 2006	24-hour dietary recalls (telephone-administered)
September 2005 – August 2006	In-home visits 12 months post-diagnosis
September 2006 – August 2007	In-home visits 24 months post-diagnosis*

*Grant time period is 3 years starting July 1, 2004, so a no-cost extension is anticipated to be required for follow-up on all 250 participants for 24 months.

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Appendix A
Lifestyle Changes Questionnaire

250 PCaP Follow-up Study Lifestyle Changes Questionnaire

Question 1.

This question asks you to compare foods that you ate a year before you were diagnosed with prostate cancer to foods that you eat now. To answer this question, for each food listed (1) indicate whether you ate the food during the year BEFORE DIAGNOSIS, then (2) indicate if you changed your consumption of this food AFTER DIAGNOSIS.

FOOD ITEM	BEFORE DIAGNOSIS Did you eat this?		AFTER DIAGNOSIS Did you change your consumption?				
	Yes	No	No change	<u>Decreased</u>		<u>Increased</u>	
				A Little	A Lot	A Little	A Lot
Whole milk products	Y	N	Z	D1	D2	I1	I2
Reduced-fat milk products	Y	N	Z	D1	D2	I1	I2
Cheese	Y	N	Z	D1	D2	I1	I2
Reduced-fat cheese	Y	N	Z	D1	D2	I1	I2
Red meat	Y	N	Z	D1	D2	I1	I2
Pork	Y	N	Z	D1	D2	I1	I2
Poultry	Y	N	Z	D1	D2	I1	I2
Fish	Y	N	Z	D1	D2	I1	I2
Whole eggs	Y	N	Z	D1	D2	I1	I2
Vegetables	Y	N	Z	D1	D2	I1	I2
Tomatoes and tomato products	Y	N	Z	D1	D2	I1	I2
Fruit	Y	N	Z	D1	D2	I1	I2
Soy products (e.g. tofu)	Y	N	Z	D1	D2	I1	I2
Whole grains	Y	N	Z	D1	D2	I1	I2
Sugar	Y	N	Z	D1	D2	I1	I2
Fried foods	Y	N	Z	D1	D2	I1	I2
Grilled foods	Y	N	Z	D1	D2	I1	I2
Pizza	Y	N	Z	D1	D2	I1	I2
Hamburgers	Y	N	Z	D1	D2	I1	I2
Other fast foods	Y	N	Z	D1	D2	I1	I2
Candy	Y	N	Z	D1	D2	I1	I2
Nuts	Y	N	Z	D1	D2	I1	I2
Regular ice cream	Y	N	Z	D1	D2	I1	I2
Cakes/sweet desserts	Y	N	Z	D1	D2	I1	I2
Vegetable oil	Y	N	Z	D1	D2	I1	I2
Margarine/shortening	Y	N	Z	D1	D2	I1	I2
Butter	Y	N	Z	D1	D2	I1	I2
Wine	Y	N	Z	D1	D2	I1	I2
Beer	Y	N	Z	D1	D2	I1	I2
Spirits/hard liquor	Y	N	Z	D1	D2	I1	I2

Question 2a. Did you consume added fat on cooked foods prior to diagnosis? Yes No

Question 2b. After diagnosis, did you change your consumption of added fat to cooked foods?
 No change Decreased a lot Decreased a little Increased a little Increased a lot

Question 3.

This question asks you to compare supplements that you consumed a year before you were diagnosed with prostate cancer to supplements that you consume now. To answer this question, for each supplement listed (1) indicate whether you consumed the supplement during the year BEFORE DIAGNOSIS, then (2) indicate if you changed your consumption of this supplement AFTER DIAGNOSIS.

SUPPLEMENT ITEM	BEFORE DIAGNOSIS		AFTER DIAGNOSIS				
	Did you consume this?		Did you change your consumption?				
	Yes	No	No change	<u>Decreased</u>		<u>Increased</u>	
				A Little	A Lot	A Little	A Lot
Multivitamin	Y	N	Z	D1	D2	I1	I2
Vitamin C	Y	N	Z	D1	D2	I1	I2
Vitamin E	Y	N	Z	D1	D2	I1	I2
Calcium	Y	N	Z	D1	D2	I1	I2
Selenium	Y	N	Z	D1	D2	I1	I2
Beta-carotene	Y	N	Z	D1	D2	I1	I2
Vitamin A + beta-carotene	Y	N	Z	D1	D2	I1	I2
Lycopene	Y	N	Z	D1	D2	I1	I2
Antioxidant mixtures	Y	N	Z	D1	D2	I1	I2
Folate (folic acid)	Y	N	Z	D1	D2	I1	I2
Saw palmetto	Y	N	Z	D1	D2	I1	I2
Fish oils	Y	N	Z	D1	D2	I1	I2
Flaxseed/Flaxseed Oil	Y	N	Z	D1	D2	I1	I2

Question 4a. Did you engage in physical activity before diagnosis with prostate cancer? Yes No
 (examples of physical activity: walking for exercise, lifting weights, jogging, aerobics, swimming)

Question 4b. After diagnosis, did you change your physical activity?
 No change Decreased a lot Decreased a little Increased a little Increased a lot

Appendix B
24-Hour Dietary Recall Script

Subject ID: «SUBJECT ID»
Name: «FNAME» «LNAME»
Home phone: «HOME PHONE»

250 PCaP Follow-up Study

24-Hour Dietary Recall

BEGIN Phone Interview

Introduce yourself.
Be friendly and relaxed.
Give neutral responses to whatever participant tells you.

Hello, my name is (_____). May I please speak with _____(NAME)? *(If person that answers is not the subject, please introduce yourself again, if not proceed with script).*

I am calling from the University of North Carolina in Chapel Hill about the 250 PCaP Follow-up Study. Thank you for agreeing to be in the study and taking the time to do this interview. Now I would like to interview you about what you had to eat and drink in the last 24 hours. This interview will take about 20-30 minutes. Let me remind you that your name and answers will be kept confidential. That means that your answers will be combined with other subjects' answers and your name will never be used in any report.

(Record the answer to this question in the tracking system)

I would like to ask you to try to remember everything you ate and drank yesterday, which was (Day of the Week). Please start telling me about what you ate and drank yesterday beginning when you first woke up to when you went to sleep.

Entering the NDS-R Quick List

The interviewer proceeds by asking the participant to make a list of all the foods and beverages they had yesterday. Say: **First, we'll make a list in the computer of what you ate yesterday starting with when you got up. Then I will ask you some more questions and we'll figure out how much you had to eat. Do you have any questions?**

- Pause, wait for and respond to questions, and proceed: **What was the first time you had something to eat or drink?** Enter the response then as needed say: **What did you have at that time?**
- Enter participant's response on the NDS-R Quick List screen. Use a slash to begin each new meal. Try not to interrupt, and allow participant to say whatever comes to mind.

Reviewing the NDS-R Quick List

Verify Quick List by reading it back to the participant saying: **I am going to read back what you have told me. Let me know if you want to add or change anything. Can you think of anything else you ate or drank yesterday that we haven't put on the list? Do you remember if you got up during the night (after midnight) and had anything to eat or drink? Did you have any afternoon snacks or anything before bed?**

- Any errors should be corrected, and any additional foods the participant may report are added at this time.

Collecting Meal Information Detail

Begin by saying: **Next we'll go over our list and I will ask you some questions about each food.**

- NDS-R will bring up the Meal Information window. Ask questions about meal time, meal name, and meal location if needed.

Asking About Additions

The interviewer will be asking about additions to every food. An on-line prompt will remind you to say: **The first thing on your list is (NDS-R inserts the name of each food).**

- Then, reading from the NDS-R screen the interviewer will say: **Did you add anything to the (NDS-R inserts the name of the food)?**
- Ask the additions question until you receive a "no" response.

Collecting Complete Food and Amount Detail

The NDS-R Food Search window prompts the interviewer for each available level of detail during this third pass. An on-line prompt will remind you to begin by saying: **What type of (insert name of food) was it?**

- The interviewer continues to define the food, selecting food variables as required on each screen. Unknown should be entered if the participant cannot describe food in detail (e.g., if it was prepared at a restaurant). If the food was prepared at home by someone other than the participant and the participant is unaware of the ingredients used, a note should be made to have the participant ask that person after the interview. An on-line prompt for the amount will remind you to say: **How much did you eat (drink)? How much did you eat (drink)?**

- Some foods require additional quantity details, with required fields indicated in yellow. After entering the amount provided by the participant, the NDS-R displays a conversion to a common unit. At this time, the interviewer must be able to visualize the amount reported and confirm as needed any questionable amounts using the Food Amounts Booklet or by making reference to other familiar items or recognizable standards. For example, 1/16 of a hamburger should have a note saying, “ate only one bite” or 8 cups of popcorn should have a note saying, “ate entire box at the movies”.
- The interviewer should ask if the complete amount described was eaten: **Were you able to finish that? or the *(insert name of food)*?**
- Note: Foods that do not have complete descriptive and/or complete amount information are indicated with a blue question mark to the left of the food. When the interviewer has completely described a food, NDS-R replaces the question mark with a green check mark to the left of each completed item.
- As the interviewer conducts the 24-hour dietary recall, he/she will provide positive reinforcement by stating “you are doing a good job, working hard, a big help” as appropriate. The interviewer should maintain a pleasant tone of voice and avoid responding to the participant in any negative ways. If it is necessary to ask the participant to repeat what he/she said, the interviewer should ask him/her to do so in a gentle way and take ownership by saying: **Sometimes it’s hard for me to hear things. Could you please tell me that again?**

Reviewing the Recall

During the fourth pass probe for missed meals, beverages, and snacks, making sure no information was inadvertently omitted. Look for missed meals. Make note of missing meals, beverages, and condiments. Read back each food and amount, asking for confirmation from the participant. For example: **Now we’ll go over what I’ve put in the computer one last time. The first thing that I have is at *(insert meal name and time)* when you had *(insert food name)*.**

- When the interviewer notices a large time gap he/she should ask: **Did you have anything to eat or drink before your *(insert time e.g., evening meal)* and *(before bed)*?**
- Additional foods and meals are inserted at any time. If the participant hesitates and can’t remember eating anything for a long period of time, the interviewer may say: **Can you think what you were doing (*at dinner/supper time, etc.*)? Sometimes if we think about where we were or whom we were with, it helps to remember what we ate.**
- The process continues until each food has been reviewed and each meal has an activity code assigned to it.

Completing the Trailer Tab

When complete, the system presents the Trailer tab and DR interviewer ends the recall saying: **Next *(insert name of participant)*, in terms of the amount of food you ate, would you say this was close to the amount that you usually eat, a lot more than you usually eat, or a lot less than you usually eat?**

- This question refers to the overall amount of food for the day, not the type of food. The interviewer records the participant response to the last question on the Trailer tab. If the participant reports a lot more, check “considerably more than usual” or a lot less than usual, check “considerably less than usual”. In either case, NDS-R requires the interviewer to provide a note that briefly states why the intake was not usual. For example, a celebration meal with lots of food or participant not feeling well and not eating much can result in eating a lot more or a lot less than usual. If needed, the interviewer can say: **What makes you say it’s (a lot more or a lot less than usual)?**
- Determine the reliability of the data. If the dietary recall is unreliable because the participant was unable to recall one or more meals or for some other reason question the reliability, he/she will click the appropriate NDS-R button and add the required NDS-R Note. Do not ask the participant this question, nor share your opinion with them.

Thank the Participant

- Thank the participant and ends the recall: **Thanks so much for your help. Do you have any questions?**
- Pause, wait for and response to questions, and proceed: **You did a great job and I really enjoyed talking with you. Remember to keep the Food Amounts Booklet in a safe place because we will need to use it when we do this again.**
- If you need the person who prepared the food to clarify items in the recall say: **Would you mind asking *(person who prepared the food, e.g. your wife, your son, etc)* about *(insert question)*?**
- Thank you. Good bye.

Appendix C
24-Hour Dietary Recall Telephone consent

250 PCaP Follow-up Study Telephone Consent

IRB Study # 04-2469

Hello, my name is _____. I am a staff member from the University of North Carolina at Chapel Hill conducting research about prostate cancer for the 250 PCaP Follow-up Study. The enrollment specialist at the 250 PCaP Follow-up Study informed us that she spoke with you and that you are eligible to participate in the study. Your participation in this research is completely voluntary. This means that you do not have to participate in this research unless you want to.

The purpose of this research study is to learn more about the general lifestyle behaviors of men with prostate cancer, any behavioral changes after diagnosis - particularly those behaviors related to diet, the use of dietary supplements and physical activity - and the impact of behaviors on cancer progression. A total of approximately 250 men with prostate cancer from a 24-county area of North Carolina will take part in this study.

If you decide to participate today, you will be asked to complete a series of questions about what you had to eat and drink in the last 24 hours. This should take about 20-30 minutes. There is a small chance that some of the questions may make you feel uncomfortable. You don't have to answer those questions if you don't want to. In fact you don't have to answer any question that you choose not to answer. And that is fine. We will just skip that question and go on to the next one.

All the information I receive from you by phone, including your name and any other identifying information, will be strictly confidential and will be kept under lock and key. I will not identify you or use any information that would make it possible for anyone to identify you in any presentation or written reports about this study. When I finish with all the phone interviews from everyone who has agreed to participate, I will group all the answers together in any report or presentation. There will be no way to identify individual participants.

The only risk to you might be if your identity were ever revealed. But I will not even record your name with your responses, so this cannot occur. There are no other expected risks to you for helping me with this study. There are also no expected benefits for you either. Although this study will not provide a benefit to you directly, it may lead to information that may benefit men diagnosed with prostate cancer in the future.

This study also includes two in-home interviews. However, a separate consent will be collected for the in-home interviews. In other words, if you agree to participate in the telephone interview today, you do not have to participate in the in-home interviews should you decide you do not want to continue in the study.

This study is being paid for by the Department of Defense and is being carried out by Dr. Susan Steck-Scott at the University of North Carolina at Chapel Hill. Portions of Dr. Steck-Scott's research team's salaries are being paid by this funding.

Do you have any questions?

You can also call Dr. Susan Steck-Scott at 1-866-340-5361 with questions about the research study. All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously if you wish, the Public Health IRB at 919-966-9347 or by email to IRB_subjects@unc.edu.

Do I have your permission to begin asking you questions?